Monday, March 4, 1991
Poster Displayed: 2:00PM–5:00PM
Hall F, West Concourse

PROMASYS - A PROTOCOL MANAGEMENT SYSTEM FOR CLINICAL STUDIES

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Promasys is a multi-user relational database system for management and control of clinical studies. It provides a centralized storage and backup facility for all study related data and gives researchers on-line concurrent access to their study data. Promasys is written in English and has a Lotus-like menu interface, with Pop-Up windows. It is developed in the 4th GL Progress (with SQL support) which is available on a large number of hardware platforms.

Promasys divides each clinical study into a number of distinct phases, each with a pre-defined set of permitted actions. This concept, combined with audit-trail, dual entry, freezing of data and extensive security features, ensures data integrity and study consistency.

The system contains an easy-to-use study definition editor. Entry criteria can be specified, which are validated upon enlistment of subjects. Multiple timetables for a study can be created, defining the study endpoints together with expected limits. The program will generate labels for sample tubes as well as customized data collection forms. Information about the study centre in which a subject participates is stored, allowing for administrative management of multi-centre studies. Promasys contains a number of standard reports, but new reports can be built into it, with full security features. The system will import load files generated by other software, while guarding the consistency of the database. Data entry can only be performed after formal approval of the protocol by an ethics committee: Promasys will check all results against defined limits and will warn against violation of these limits. Treatment codes for double-blind studies will not be revealed during the execution phase.

Promasys is designed to provide research staff with a flexible tool for managing clinical trials in a uniform way. It controls a clinical study from study design to the analysis and storage of data. Promasys offers a user-friendly export facility, leaving users free in the choice of their statistical-, graphics- or wordprocessing programs.

PACKAGE FOR EVALUATION OF RECEIVER OPERATOR CHARACTERISTIC CURVES

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The Receiver Operator Characteristic (ROC) curves characterise multivariate sets of clinical data used for identification of patients at high risk. For the comparison of the clinical usefulness of different multivariate sets of data, the corresponding ROC curves have to be compared. This may prove difficult as such comparisons also depend on the clinical targets of the identification of high risk patients. In order to serve such an evaluation of ROC curves, a special computer program has been developed which computes non-linear area integrals of ROC curves. The program is based on the following idea. If the stratification of patients at high risk of future complications is aimed at leading to an expensive treatment or at a treatment exposing the patients to a higher risk (such as the treatment of post AMI patients with implantable defibrillators), the reduction of false positive cases is more important than the reduction of false negative cases. If, on the contrary, the expected treatment of the stratified patients is inexpensive and virtually risk free (such as the treatment of post AMI patients with Aspirin), the reduction of false negative cases is more important than the reduction of false positive cases. In the first case, the multivariate set of clinical data which provides high values of specificity for low values of sensitivity has to be found, whilst in the second case, high values of specificity are needed for high values of sensitivity.

For the purposes of the evaluating program, the importance of a particular range of values of sensitivity is expressed in mathematical terms by a non-linear measure on the space of sensitivities. For each analysed ROC curve, the program computes the non-linear area integral of the curve according to the given measure. The program inputs the results of another special package which computes the ROC curves, and in an interactive mode, the measure on the space of sensitivities is designed. The integral of the ROC curve is then computed; the result is obtained almost instantly. The current version of the program also contains five pre-defined sensitivity measures. One of them does not prefer any range of sensitivity and provides the mean values of specificity for all possible values of sensitivity. The other four measures represent weak and strong preferences of high and low values of sensitivity. The package is being used in studies stratifying patients at high risk of complications after myocardial infarction.

Tuesday, March 5, 1991
Poster Displayed: 9:00AM–12:00NOON
Hall F, West Concourse

COMPUTER RECOGNITION OF CORONARY ARTERIES

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Although several computer-based approaches exist to assess coronary artery structure and function radiographically, the widescale application of these techniques has been limited by the need for manual identification of anatomic landmarks. We have developed a new approach for the totally automated recognition of the arteries, potentially replacing the need for tedious operator interaction. Mathematical templates are used to model the characteristics of arterial structures, providing *a priori* knowledge to drive structure identification. New templates are created using an interactive program to identify arterial segments in training images. A dynamic search algorithm finds the most probable mapping of the templates onto the data in the image to be analyzed, providing reliable handling of discontinuities (such as high-grade stenoses). This approach has several unique advantages: (1) works on unprocessed, unsubtracted, and even noisy arteriograms; (2) image segmentation (distinguishing artery from non-artery) is always context-dependent; and (3) continued refinement is possible using additional training images.

A frame from a sample arteriogram is shown below on the left. On the right is the result of matching a "left anterior descending" template to the image. Less probable paths are shown in black (discarded by the dynamic search process), and the highest probability path is shown in white. Totally automated coronary artery recognition is feasible, and has the potential for having major impact on diagnostic, therapeutic, and research endeavors in coronary disease.

A MULTIUSER SYSTEM FOR THE QUALITATIVE AND QUANTITATIVE EVALUATION OF CARDIAC ANGIOGRAPHY

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A number of computer systems are available to aid in analyzing catheterization data, but few can collect both extensive qualitative morphologic data as well as quantitative information on a large number of patients in a timely fashion. In addition, most systems do not find widespread use due to their relatively complex user interface. We have developed the Duke University Quantitative/Qualitative Catheterization Evaluation System (DUQUES), a complete analysis system which can be used on a routine basis in a variety of clinical and research environments. The system allows for comprehensive data collection of morphologic features in conjunction with a wide range of quantitative ventriculographic and coronary anatomic details. These data can be merged with other database resources for a complete catheterization report with all variables searchable.

The imaging core laboratory consists of a DEC VAXstation 3500 performing as an image librarian and relational database server to five networked VAXstation 3100 workstations. The VS3500 provides a link to a Gould IP8400 image processor for computation-intensive applications. Because of its multiuser design, all system operations can be performed on any of the workstations simultaneously. The number of workstations and their locations can be changed as desired to support multiple studies and can also be extended to remote sites using high speed modems. A graphical user interface(GUI) has been developed using OSF/Motif, an industry standard X11.4 graphics windowing system, giving the DUQUES system the ability to operate on a variety of computer platforms. The GUI is used for the presentation and manipulation of images as well as the entry of data on the same display. Coronary lesion data is displayed on an individualized coronary tree diagram. Quantitative lesion measurements can be performed in less than a minute per lesion. The DUQUES system has been recently utilized in a 600 patient restenosis study. Its operation can be readily applied to any busy research or clinical environment.